

10/732,848  
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## Status of Claims:

Claims 1-7 and 28-32 were rejected. Claims 32 has been amended. Claims 8-27 have been cancelled. New claims 33-39 have been added. All of the amendments are fully supported by the specification, claims, and figures as originally filed. No new matter is believed or intended to be involved.

§102 Rejections

Claims 1, 4-7, and 30-32 were rejected under 35 U.S.C. §102(b) as being anticipated by Hibner et al. (U.S. 6,120,462). Under MPEP 2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim, and the elements must be arranged as required by the claim. Under this standard, Applicant submits that Hibner et al. fails to anticipate any of the amended independent claims.

Independent claim 1 recites "a first mechanism for advancing the cutter" and "a second mechanism for advancing the cutter." Hibner et al. fails to explicitly or inherently teach or suggest such limitations, particularly in the arrangement required by independent claim 1. The Office has cited Col. 4, lines 49-56 as teaching the first and second mechanisms recited in claim 1. However, a reading of the passages cited by the Office reveals that the cited teachings actually relate to a method of using a biopsy instrument, without any discussion of two mechanisms being used to advance the cutter. In fact, a further reading of Hibner et al. reveals that the advancement of the cutter is explicitly taught as being provided by a single mechanism rather than two – a translation motor (item no. 340) and its associated components. Translational speed variation is provided by varying the control signal to the translation motor. (See, e.g., Col. 19, line 36 through Col. 20, line 28 and FIGS. 17A-17E of Hibner et al.). Applicant submits that one of ordinary skill in the art would not read the first and second mechanisms recited in claim 1 on the single mechanism for advancing the cutter explicitly disclosed in Hibner et al. Accordingly, Applicant respectfully submits that Hibner et al. fails to anticipate independent claim 1 in accordance with MPEP 2131, and respectfully requests that the rejections be withdrawn.

Similarly, amended independent claim 32 recites "a first mechanism for advancing the cutter" and "a second mechanism for advancing the cutter." Amended independent claim 32

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further recites that "the second mechanism has at least one component that is not in the first mechanism." For at least the same reasons that Hibner et al. fails to anticipate claim 1 as noted above, Hibner et al. fails to anticipate amended independent claim 32 in accordance with MPEP 2131. Applicant therefore respectfully requests that the rejections be withdrawn.

### §103 Rejections

Claims 2 and 3 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hibner et al. in view of Miller et al. (U.S. 6,638,235). Claims 28 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hibner et al. in view of Wright (U.S. 4,662,869). Under MPEP 2143, in order to establish a *prima facie* case of obviousness, the prior art reference or combination of references must teach or suggest all of the limitations of a claim. A *prima facie* case of obviousness also requires that there be some teaching suggestion, or motivation to modify the references either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP 2143.01. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

Applicant notes that claims 2, 3, 28, and 29 each depend from independent claim 1. As discussed above, Hibner et al. fails to explicitly or inherently teach or suggest all of the limitations of claim 1. Applicant further submits that the remaining references cited by the Office fail to make up for such deficiencies of Hibner et al. The combined art of record therefore fails to render independent claim 1 obvious in accordance with MPEP 2143.03. The combined art of record also fails to render any of claims 2-7, 28-31, and 32-39 obvious for at least the same reasons, among others. Applicant therefore respectfully requests that the rejections be withdrawn.

Furthermore, even if the combined art of record taught or suggested all of the elements of any of the independent claims, the art is devoid of any suggestion or motivation to modify or combine the teachings of the references in order to obtain the claimed invention. Indeed, MPEP 2143.01 admonishes that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (emphasis in original). *Actual evidence* of a suggestion, teaching, or motivation to combine prior art references must be shown. *In re Dembiczack*, 50 USPQ2d 1614 (Fed. Cir. 1999). The Office has provided no evidence of a motivation as of the date of the invention to modify or combine the

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teachings of the prior art. Because the requisite evidence of motivation required by MPEP 2143.01 is lacking, Applicant respectfully requests that the rejection be withdrawn.

Beyond the foregoing shortcomings with respect to the rejections of the independent claims, Applicant further notes that the dependent claims include additional limitations not taught or suggested in the art of record, thus forming independent basis for novelty and non-obviousness.

To the extent that the present amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments. While Applicant has noted several distinctions over the art of record, Applicant notes that several other distinctions exist, and Applicant preserves all rights and arguments with respect to such distinctions.

Applicant notes that the arguments made herein relate solely to the patentability of the claims currently being prosecuted in the present application. No statements or arguments made herein are intended to speak to the scope of the claims in the Hibner et al. patent. These remarks should therefore not be read as having any effect whatsoever on the coverage provided by the claims set forth in Hibner et al.

#### Conclusion

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance.

Respectfully submitted,

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## UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICATION NO.                                                                                       | FILING DATE | FIRST-NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/732,848                                                                                            | 12/10/2003  | Chris Cicenas        | END-5006NP          | 8794             |
| 27777                                                                                                 | 7590        | 06/16/2006           | EXAMINER            |                  |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | ROY, ANURADHA       |                  |
|                                                                                                       |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                                                       |             |                      | 3736                |                  |

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

09/14/2006 THU 10:12 FAX

SEP 14 2006

010/015

**Office Action Summary**

10732,848

CICENAS ET AL.

Examiner

Art Unit

Anuradha Roy

3736

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 March 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 28-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION****Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 – 7, & 30 – 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hibner et al. (US Patent No. 6,120,462).

With regard to claim 1, Hibner et al. discloses a biopsy device (Figure 1) comprising:

- ❖ a hollow biopsy needle (70) having a lateral tissue receiving port (78);
- ❖ a hollow cutter (96) advancable within the biopsy needle;
- ❖ a first mechanism (Column 4, lines 49-54) for advancing the cutter (96) to a position proximal of the lateral tissue receiving port (78);
- ❖ and a second mechanism (Column 4, lines 54-56) for advancing the cutter (96) distal of said position proximal of the lateral tissue receiving port (78).

Regarding claim 4, Hibner et al. discloses a biopsy device, wherein said second mechanism rotates and advances said cutter (Column 4, line 64 - Column 5, line 1).

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In regards to claim 5, Hibner et al. discloses a biopsy device, wherein the first mechanism advances the cutter at first rate, and wherein the second mechanism advances the cutter at a second rate (Column 4, lines 46-56). Examiner contends that there are two predetermined translational speeds, thus there are a first rate and second rate.

Regarding claims 6 & 7, Hibner et al. discloses a biopsy device, wherein the first rate is different from the second rate and the first rate is greater than the second rate (Column 3, lines 12-16, 27-35, 47-52 & Column 19, line 36 – Column 20, line 30). Examiner contends the reduction of translational speed in response to the cutting resistance is analogous to the slower second rate, as disclosed by Applicant.

Regarding claim 30, Hibner et al. discloses a biopsy device, wherein the first mechanism is capable of advancing the cutter without the rotation of the cutter, and wherein the second mechanism advances and rotates the cutter (Column 4, lines 64 – Column 5, line 1)

In regard to claim 31, Hibner et al. discloses a biopsy device, wherein the second mechanism advances the cutter from a position proximal of the tissue receiving port to a position distal of the tissue receiving port (Column 4, lines 54 – 56).

Regarding claim 32, Hibner et al. discloses a biopsy device (Figure 1) comprising:

- ❖ a hollow biopsy needle (70) having a lateral tissue receiving port (78);
- ❖ a hollow cutter (96) advancable within the biopsy needle, the hollow cutter (96) having an open distal end (97);

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- ❖ a first mechanism (Column 4, lines 49-54) for advancing the distal end of the cutter (96) to a position proximal of the lateral tissue receiving port (78); and
- ❖ a second mechanism (Column 4, lines 54-56) for advancing the distal end of the cutter (96) to a position distal of the lateral tissue receiving port (78).

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 & 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibner et al. in view of Miller et al. (US Patent No. 6,638,235).

Regarding claims 2 & 3, Hibner et al. discloses a biopsy device with all of the aforementioned elements. However, Hibner et al. does not disclose a biopsy device, wherein the first mechanism employs a pressure differential or pneumatics for advancing the cutter. Miller et al., however discloses a biopsy device employing pressure differentials and pneumatics (Column 8, lines 1-14). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Miller et



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al. to incorporate pneumatics and pressure differentials with Hibner et al. in order to provide a means to drive the cutter.

#### **Additional Claim Rejections - 35 USC § 103**

Claims 28 & 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (US Patent No. 4,662,869).

In regard to claims 28 & 29, Hibner et al. discloses a biopsy device with all of the aforementioned elements. However, Hibner et al. does not disclose a biopsy device, wherein at least one of the first and second mechanisms comprises a piston and wherein the piston is non-rotating. Wright, however, does disclose a biopsy device, wherein in at least one of the first and second mechanisms comprises a piston (158) and wherein the piston is non-rotating (Column 3, lines 57 – 58). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Wright to incorporate a non-rotating piston with Hibner et al. in order to orient the piston ultimately with the housing (Column 3, line 60 – 62).

#### ***Response to Arguments***

Applicant's arguments, see Remarks, filed on March 8, 2006, with respect to claims 1-7 have been fully considered and are persuasive. The original rejections of claims 1-7 have been withdrawn.

#### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can

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normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~

  
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